

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Yougandh Chitre, et al.**Serial No.:** 10/656,649**Examiner:** K. Schaetzle**Filed:** September 4, 2003**Art Unit:** 3766**Docket No.:** A03P1061**For:** MEDICAL ELECTRICAL LEAD PROVIDING FAR-FIELD SIGNAL
ATTENUATION

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being e-
filed on:

April 30, 2007
Melinda E. Hallmark 4/30/07
Melinda E. Hallmark Date

DECLARATION UNDER 37 CFR 1.132

I, Yougandh Chitre, declare that:

- 1) I am one of the named co-inventors of the above-identified patent application, which was filed on September 4, 2003.
- 2) I had built and tested an active fixation lead with the helix serving as the cathode electrode, and a ring electrode spaced 1.1 millimeters from the helix electrode acting as the anode electrode (the "test lead"). I tested the lead in the right ventricle of several canines.
- 3) I also tested a commercially available Riata® active fixation lead with spacing of 10 millimeters between the cathode (helix) and anode (ring) electrodes (the "control lead").
- 3) I tested the two leads with the same model of implantable cardioverter defibrillator (ICD), namely an EpicTM+ DR model device.
- 4) For the control lead, the T-wave amplitude following paced ventricular events averaged 1.7 mV (Exhibit A), and for the test lead the T-wave amplitude following paced ventricular events averaged 0.4 mV (Exhibit B).

5) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

04125107

Date



Yougandh Chitre

17 Jun 2007 13:31:17

Smithers
Epic™ DR Model V-239, Serial 242675

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Smithers
Epic™ DR Model V-239, Serial 242675



Lead	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
Amplitude (mV)	1.50	1.35	1.26	1.46	1.36	1.42	1.42	1.42	1.42	1.42	1.42	1.42
PR (ms)	166	162	162	162	162	162	162	162	162	162	162	162
QR (ms)	162	162	162	162	162	162	162	162	162	162	162	162
RV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
AV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
SV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
TV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
AV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
SV (ms)	162	162	162	162	162	162	162	162	162	162	162	162
TV (ms)	162	162	162	162	162	162	162	162	162	162	162	162

Control Lead: SJM's Riata
(Tip - Ring Spacing 10 mm)



T-Wave Amplitude: (3.4 mV/cm X 0.5 cm) = 1.7 mV

25.0 mm/sec

25.0 mm/sec

Position 1: Surface ECG (1.7 mV/cm)
Position 2: A Sense/Pace (5.4 mV/cm, ±1.0 mV)
Position 3: V Sense/Pace (3.4 mV/cm, ±0.9 mV)

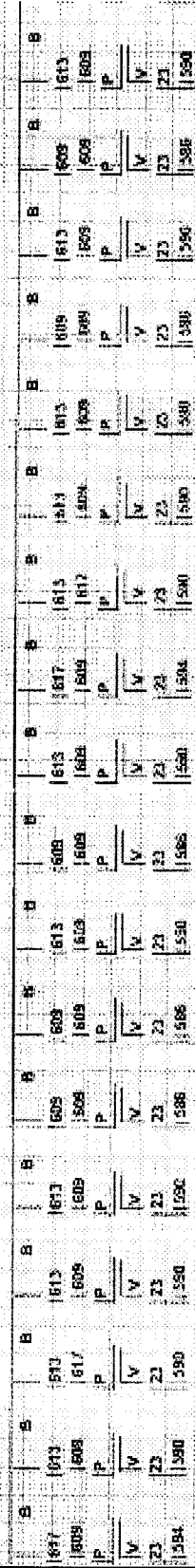
Position 1: Surface ECG (1.7 mV/cm)
Position 2: A Sense/Pace (5.4 mV/cm, ±1.0 mV)
Position 3: V Sense/Pace (3.4 mV/cm, ±0.9 mV)

29 Jan 2007 12:50:50

Homert
Epic™ DR Model: V-239, Serial: 239585

79 Jan 2007 12:58:55

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Epic™ DR Model: V-239, Serial: 239585



Experimental Lead: FSR
(Tip - Ring Spacing 1.1 mm)



T-Wave Amplitude: (1 mV/cm X 0.4 cm) = 0.4 mV

25.0 mm/sec

25.0 mm/sec

Position 1: Surface ECG (0.975 mV/cm)
Position 2: A Sense/Pace (3.9 mV/cm, 23.0 mV)
Position 3: V Sense/Pace (9.0 mV/cm, 58.9 mV)

Position 1: Surface ECG (0.975 mV/cm)
Position 2: A Sense/Pace (3.9 mV/cm, 23.0 mV)
Position 3: V Sense/Pace (9.0 mV/cm, 58.9 mV)

3511P Serial: 11608 (3307 - 6.11m)

3510P Serial: 11585 (3307 - 5.11m)

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